



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Teresa Stank Rea
Buchanan Ingersoll PC
PO Box 1404
Alexandria VA 22313-1404

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,656,667

JAN 24 2007

NOTICE OF FINAL DETERMINATION
AND
REQUIREMENT FOR ELECTION

A determination has been made that U.S. Patent No. 5,656,667, which claims a method of use of the human drug product OMACOR® (EPA ethyl ester and DHA ethyl ester), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,476 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent and an express election of the patent for which the certificate of extension will issue may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period.

Applicant also has applied for patent term extension of U.S. Patent Nos. 5,502,077 and 5,698,594 based on the regulatory review period for the human drug product OMACOR® (EPA ethyl ester and DHA ethyl ester).

When patent term extension applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the patent having the earliest date of issuance unless applicant elects a different patent. In the absence of an election by applicant within one month of the date of this notice, and in accordance with 37 CFR 1.785(b), the applications for patent term extension in U.S. Patent Nos. 5,698,594 and 5,656,667 will be denied. Accordingly, the application for patent term extension of the patent having the earlier date of issuance will be granted (i.e., a certificate of extension will be issued to U.S. Patent No. 5,502,077.) In the absence of such request for reconsideration and if U.S. Patent No. 5,656,667 is elected, the Commissioner will issue to the applicant for extension of the term of U.S. Patent No. 5,656,667, a certificate of extension, under seal, for a period of 1,476 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of February 2, 2006, (71 Fed. Reg. 5669). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (3,408 - 1,064) + 304 \\ &= 1,476 \text{ days (4.0 years)}\end{aligned}$$

Since the regulatory review period began September 14, 1994, before the patent issued (August 12, 1997), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From September 14, 1994, to and including, August 12, 1997, is 1,064 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,656,667
Granted:	August 12, 1997
Original Expiration Date ¹ :	August 12, 2014
Applicant:	Harald Breivik, et al.
Owner of Record:	Pronova Biocare AS
Title:	Fatty Acid Composition
Product Trade Name:	OMACOR® (EPA ethyl ester and DHA ethyl ester)
Term Extended:	1,476 days
Expiration Date of Extension:	August 27, 2018

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450. By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.



Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 7
5600 Fishers Lane (Rockwall II Rm. 1101)
Rockville, MD 20857

Attention: Beverly Friedman

RE: OMACOR® (EPA ethyl ester
and DHA ethyl ester)
FDA Docket No.: 2005E-0258

¹Subject to the provisions of 35 U.S.C. § 41(b).